In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

VIRGINIA VAN ZANDT,	*	
	*	No. 19-746V
Petitioner,	*	Special Master Christian J. Moran
	*	
	*	Filed: May 13, 2022
v.	*	
	*	Entitlement; bench ruling; influenza ("flu")
	*	vaccine; Guillain-Barré syndrome; back
SECRETARY OF HEALTH	*	pain; on-Table claim; onset.
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Bridget McCullough, Muller Brazil, LLP, Dresher, PA, for petitioner;
Katherine Esposito, U.S. Dep't of Justice, Washington, DC, for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION[1]

Virginia Van Zandt alleged that she received an influenza vaccine and developed Guillain-Barré syndrome within the time listed on the Vaccine Injury Table. Although the parties agreed that Ms. Van Zandt received a flu vaccine and she developed Guillain-Barré syndrome, they disagreed as to whether the onset occurred within the time listed on the Vaccine Injury Table. For the reasons explained below, a preponderance of evidence indicates that Ms. Van Zandt developed a symptom of her Guillain-Barré syndrome before the vaccination. Thus, she is not entitled to compensation.

Abbreviated Procedural History

Ms. Van Zandt alleged that an influenza ("flu") vaccine she received on November 6, 2017 caused her to suffer Guillain-Barré syndrome ("GBS"), an injury contained on the Vaccine Injury Table ("Table"). Pet., filed May 20, 2019, at ¶ 2, 20. Although Ms. Van Zandt contemplated pursuing other causes of action, she eventually proceeded only upon the on-Table claim. Pet'r's Status Rep., filed June 14, 2021.

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. The posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

The key issue is when Ms. Van Zandt's GBS first manifested. Ms. Van Zandt proposed an onset date of November 13, 2017. See Pet'r's Br., filed Nov. 17, 2021, at 3. Ms. Van Zandt relied upon the opinion of a neurologist, Frederick Nahm. Exhibit 6. In contrast, the Secretary asserted that Ms. Van Zandt's GBS began two days before her vaccination. Resp't's Br., filed Dec. 17, 2021, at 9. The Secretary based his position on the opinion of a different neurologist, Thomas Leist. Exhibit A.

A hearing was held on February 23, 2022, in San Francisco, California. During this hearing, Ms. Van Zandt, her primary care physician (Melody Lee), Dr. Nahm, and Dr. Leist testified. On May 12, 2022, an oral argument was held via videoconferencing.

After the parties submitted all evidence and completed their arguments, the undersigned found that Ms. Van Zandt failed to establish that she was entitled to compensation. An oral or bench ruling is appropriate. See Doe/17 v. Sec'y of Health & Hum. Servs., 84 Fed. Cl. 691, 704 n.18 (2008) ("Even a special master's ruling on entitlement may be delivered from the bench, with no written opinion."); see also Heddens v. Sec'y of Health & Hum. Servs., No. 15-734V, 2018 WL 5726991 (Fed. Cl. Spec. Mstr. Oct. 5, 2018), mot. for rev. denied, 143 Fed. Cl. 193 (2019).

The undersigned is issuing this document for two reasons. First, this document will become available to the public pursuant to 42 U.S.C. § 300aa-12(d)(4). Second, this document provides an abbreviated recitation for the basis of decision. See Hebern v. United States, 54 Fed. Cl. 548 (2002) (example of a judge from the United States Court of Federal Claims formalizing a bench ruling denying a motion for review).

Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Section 13(a)(1) of the Vaccine Act instructs special masters to consider "the record as a whole." As explained in the bench ruling, the undersigned considered all the evidence, including the medical records, witness, statements, expert reports, medical literature, and oral testimony. The undersigned's consideration of this evidence began when the evidence was received as outlined in the recitation of the case's procedural history. See Vaccine Rule 5. The undersigned and the parties discussed timing and the onset issue on several occasions.

Findings of Fact

A preliminary issue is whether Ms. Van Zandt's numbness and tingling predated her vaccination. The evidence on this issue is very close. Two records favor a finding that Ms. Van Zandt's numbness and tingling began after vaccination. In a November 8, 2017 email to her

primary care physician, Dr. Melody Lee, Ms. Van Zandt reported back pain for the past four days. Exhibit 2 at 1528-29. Dr. Lee asked if Ms. Van Zandt was experiencing any other symptoms, including pain down her legs, and Ms. Van Zandt stated that aside from her psoriasis, she had no other symptoms other than back pain. Id. Additionally, on November 16, 2017, neurologist Dr. Jacqueline Marcus noted that Ms. Van Zandt's numbness and tingling started after her back pain. Id. at 1899.

Conversely, two records support a finding that Ms. Van Zandt's numbness, tingling, and gait imbalance started at the same time as her back pain. On November 14, 2017, Nurse Dee Standley wrote that Ms. Van Zandt had "numbness and tingling [in] both hands and feet for 1.5 weeks." Id. at 1669. Ms. Van Zandt testified that the note is inaccurate about onset of numbness and tingling. Tr. 26. However, all other parts of Nurse Standley's note are correct, including the notation of one dose of Dilaudid. The only information Ms. Van Zandt challenged is with respect to onset of numbness and tingling. Tr. 48-49. Additionally, at a November 15, 2017 appointment with pain medicine and rehabilitation specialist Dr. Thomas Reutter, Ms. Van Zandt reported that her numbness in her hands and feet and her gait imbalance may have started at the same time as her back pain. Id. at 1721. Ms. Van Zandt believes this record is inaccurate. Tr. 50-51.

Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, it is not possible to distinguish records created on November 8 and 16, 2017, from records created on November 14 and 15, 2017. It is not necessary to resolve the question of when Ms. Van Zandt's onset of numbness and tingling occurred because the case can be resolved based on the finding that her back pain was a manifestation of her GBS.

Back pain can be a presenting symptom of GBS.[2] Both Dr. Nahm and Dr. Leist agreed that back pain can be a symptom of GBS. Tr. 144-47, 162 (Dr. Nahm); Tr. 195-96 (Dr. Leist). At the hearing, Dr. Lee also acknowledged that Ms. Van Zandt's back pain could have been a manifestation of her GBS. Tr. 108. Some potential contrary evidence comes from the van Doorn article (exhibit 10), which shows that in diagnosing GBS, the focus is on sensory and motor changes. Exhibit 10 (Peiter A. van Doorn et al., Clinical Features, Pathogenesis, and Treatment of Guillain-Barré Syndrome, 7 Lancet Neurology 939 (2008)). Dr. Nahm also states that for a patient with focal, non-radiating back pain, a GBS diagnosis would not "be [at] the top of the list." Tr. 122. Although back pain is a less common presentation for GBS, the Sanchez-Guerra article discussed examples of GBS patients with onset of pain preceding weakness.

[2] Exhibit A-2 (Masato Kinboshi et al., Pain in the Acute Phase of Guillain- Barré Syndrome, 2 Neurology & Clinical Neuroscience 50 (2014)); exhibit A-3 (D.E. Moulin et al., Pain in Guillain- Barré Syndrome, 48 Neurology 328 (1997)); exhibit A-4 (Letter from Marisa Sánchez-Guerra et al., University Hospital Marqués de Valdecilla, Severe Backache in Guillain-Barré Syndrome, to the Editor of Muscle & Nerve (Feb. 4, 2002)); see also exhibit 15 (Xianjun Ding et al., Guillain-Barré Syndrome and Low Back Pain: Two Cases and Literature Review, 13 Open Med. 503 (2018)) and exhibit 16 (Shaoli Yao et al., Pain During the Acute Phase of Guillain-Barré Syndrome, 97 Med. 34 (2018)) (case reports).

Here, the parties agree that Ms. Van Zandt experienced back pain two days before her vaccination. Exhibit 2 at 1528-29.

The ensuing question is whether the back pain could be persuasively associated with a condition other than GBS. Dr. Nahm opined that Ms. Van Zandt's back pain was due to her congenital abnormality. A CT scan on November 12, 2017, revealed Ms. Van Zandt's congenital abnormality at the T6 level of her spine. Exhibit 2 at 1567-68; Tr. 104-05 (Dr. Lee). Dr. Vivian Reyes, the emergency room ("ER") doctor, thought Ms. Van Zandt's congenital problem was the source of her pain. Exhibit 2 at 1568. Regarding the CT scan findings, Dr. Lee wrote in an email to Ms. Van Zandt, "I do find it a bit unusual that a congenital anomaly is causing you this much pain spontaneously. Nonetheless, this location does correlate well to where your pain is, so I do think it's the correct diagnosis." Id. at 1598. At hearing, Dr. Lee deferred to Dr. Reyes's conclusion that Ms. Van Zandt's back pain was caused by her congenital abnormality (Tr. 105), but could not say herself that the pain was musculoskeletal in nature. Tr. 82-83. Dr. Reyes also conducted a neurological examination on Ms. Van Zandt, which was negative. Exhibit 2 at 1564; Tr. 204-05. Dr. Leist stated that an ER doctor was unlikely to do a full neurological exam, noting that that ER exams are "very directed." Tr. 191. Therefore, Dr. Reyes's finding that Ms. Van Zandt's neurological exam was negative does not carry great weight.

Dr. Leist persuasively explained that Ms. Van Zandt's congenital abnormality, which was at the T6 level, did not explain why Ms. Van Zandt experienced pain throughout other areas of her back. Tr. 188-90; 196, 209. On November 9, 2017, Dr. Lee noted tenderness at the T10 level of Ms. Van Zandt's spine. Exhibit 2 at 1540; Tr. 80, 90-91 (Dr. Lee). At the hearing, Dr. Leist testified that the T10 level is aligned with the belly button, while the T6 level is at the nipple. Tr. 188. Dr. Lee also noted that the T6 level and T10 level are 3-4 inches apart. Tr. 92. Thus, the tenderness Dr. Lee noted at the T10 level did not align with Ms. Van Zandt's congenital abnormality at the T6 level.

Dr. Nahm maintained that Ms. Van Zandt's pain was musculoskeletal in nature because it was focal and non-radiating. Tr. 122, 140-41; 151-52, 164. Therefore, he asserted, Ms. Van Zandt was experiencing two separate issues: a structural problem and a neurological problem. Tr. 140. Three points undermine Dr. Nahm's theory.

The first issue with Dr. Nahm's theory is the coincidence in timing. Ms. Van Zandt had not experienced this type of back pain prior to November 2017 and has not experienced this type of back pain after November 2017. Dr. Nahm could not explain why Ms. Van Zandt did not experience this type of back pain prior to November 2017 or after her GBS recovery. Tr. 142-43. Dr. Leist noted that Ms. Van Zandt's congenital abnormality had been present her entire life. Exhibit A at 7. At hearing, Dr. Leist explained that if Ms. Van Zandt's congenital problem were significant, she would experience recurring problems. Tr. 198-99. Dr. Nahm could not explain why, if Ms. Van Zandt's back pain was caused by degenerative disc disease, she had not experienced problems in the last 4-5 years. He acknowledged that he would expect to see a flare. Tr. 165. The isolated nature of Ms. Van Zandt's back pain tends to suggest the back pain is related to her acute GBS, not to any long-standing problem.

The second issue with Dr. Nahm's theory is the spread of the pain. Dr. Reutter noted tenderness throughout Ms. Van Zandt's entire spine on November 15, 2017. Exhibit 2 at 1723; Tr. 190 (Dr. Leist). Ms. Van Zandt testified that Dr. Reutter seemed "triumphant" about finding the source of her back pain—the disc problem found on the MRI. Tr. 28. Dr. Reutter administered a trigger point injection to help with the pain. Exhibit 2 at 1724-25. Dr. Nahm testified that Dr. Reutter's use of a trigger point injection indicates that he believed Ms. Van Zandt's back pain was musculoskeletal. Tr. 173. However, Ms. Van Zandt testified that the trigger point injection did not alleviate her pain. Tr. 29. When asked if the fact that Ms. Van Zandt's pain did not improve with the trigger point injection indicates that the issue was neurologic, Dr. Nahm stated he "wouldn't go that far." Tr. 175. He noted that the effect of the injection wears off in one hour, and the treatment may have been insufficient to treat Ms. Van Zandt's pain. Tr. 175. Dr. Leist opined the lack of improvement from the trigger point injection pointed away from a structural abnormality. Tr. 197. Similarly, Dr. Leist commented that use of pain medication like Percocet should have given more relief to a structural problem. Tr. 197. In rebuttal testimony, Dr. Nahm could not explain why a structural problem would extend so extensively throughout Ms. Van Zandt's back. Tr. 235-36. In contrast, Dr. Leist recognized that spreading pain is more consistent with a neuropathic origin. At oral argument, Ms. Van Zandt's counsel argued that Ms. Van Zandt's back pain on November 15, 2017, could have been caused by her GBS, but her pre-vaccination back pain was not. However, Ms. Van Zandt's back pain cannot be isolated and must be evaluated in the context of the entire record.

The third flaw with Dr. Nahm's theory is that Ms. Van Zandt's back pain improved after IVIG therapy. When Ms. Van Zandt was discharged from the hospital, she was still experiencing back pain. Exhibit 2 at 2351. At a follow-up appointment with Dr. Marcus on December 18, 2017, Dr. Marcus noted that IVIG seemed to help with Ms. Van Zandt's pain. Id. at 2350. Dr. Nahm testified that because Ms. Van Zandt's back pain was ongoing at the time of discharge, it indicates that the issue was musculoskeletal. Tr. 177-79. He opined that an inflammatory or neurological condition would have resolved with IVIG. Tr. 179. When asked if the IVIG should have resolved the back pain by the time of discharge if it was neurological, Dr. Leist stated that he would expect a more gradual decline in pain over time. Tr. 226-27. He cited the Moulin article (exhibit A-3), which showed a decline in pain in GBS patients over time. He stated that Ms. Van Zandt's recovery was consistent with this. Thus, Ms. Van Zandt's improvement after taking IVIG tends to show that her underlying condition was traceable to an inflammatory cause because IVIG is given for inflammation.

The remaining evidence to consider comes from statements from Ms. Van Zandt's treating physicians. A note from Dr. Marcus on February 15, 2018 states that Ms. Van Zandt should not receive future flu shots. Exhibit 2 at 2491; see also Tr. 84-85 (Dr. Lee); Tr. 209-10 (Dr. Leist). Additionally, on October 6, 2020, Dr. Lee wrote: "Do NOT OFFER flu shot to this patient. She had a severe complication from flu shot a couple years ago." Exhibit 20 at 516. At hearing, Dr. Lee could not recall why she created this record. Tr. 85; see also Tr. 212-13 (Dr. Leist). These statements offer some support for vaccine-causation and although not dispositive, they would be worth consideration in a causation-in-fact case. However, these statements do not help resolve when Ms. Van Zandt's GBS first manifested.

Accordingly, the evidence preponderates in favor of finding that Ms. Van Zandt's back pain on November 4, 2017, two days before her vaccination, was the initial manifestation of her GBS. Therefore, Ms. Van Zandt has failed to satisfy the criteria for an on-Table claim that the flu vaccine caused her GBS. 42 C.F.R. § 100.3(a) ¶ XIV.D.

Conclusion

The undersigned directs the Clerk's Office to enter judgment based upon the decision in this case if a motion for review is not filed. When the time for filing a motion for review (see Vaccine Rule 23) begins to run is for an appellate tribunal to decide.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master